DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
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60 8th Street, N.E.
Atlanta, Georgia 30309

October 22, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Joseph J. Smith, III, President
Atlantic Seafood, Inc.
P.O. Box 440
Hampstead, NC 28443

Warning Letter
05-ATL-02

Dear Mr. Smith:

On September 14 - 16, 2004, FDA conducted an inspection of your seafood distributing and repacking facility located at or near the intersection of Highway 17 and Highway 210, Hampstead, North Carolina. During that inspection, our investigators documented serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or to otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your fresh, histamine-forming fish are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the seafood HACCP regulations through links in FDA's home page at *www.fda.gov*.

The deviations of concern are as follows:

1. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met at each of the critical control points, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for fresh histamine-forming fish lists a critical limit at the "Receiving Histamine Fish" critical control point that is not adequate to control the histamine formation hazard. Specifically, your critical limit for this critical control point does not match or otherwise apply to your firm's

operations. It is written for a primary processor that receives histamine-forming fish directly from a harvester. However, your firm receives histamine forming fish from other seafood processors. Please remember that after correcting the critical limit, the corresponding monitoring procedures will likely need to be updated to fit the new critical limit. We are enclosing a copy of *Chapter 7: Scombrotoxin (Histamine) Formation* from the third edition of the Fish & Fisheries Products Hazards & Controls Guidance for your use in developing an adequate HACCP plan for histamine-forming fish.

2. You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for histamine-forming fish does not list the hazard of histamine formation at the "Storage Cooler" critical control point. In addition, the critical limit at this critical control point, i.e. "Not above [redacted] for more than [redacted] hours," is inadequate to control the histamine formation hazard.

3. Because your HACCP plan includes corrective actions, the described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plans for fresh, histamine-forming fish at the "Storage Cooler" critical control point are not appropriate to control the histamine formation hazard. Specifically, the listed corrective actions fail to include an evaluation of the seafood product stored in the cooler at the time the critical limit was exceeded, to determine its suitability for distribution.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may recommend that the United States bring a legal action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation, such as copies of HACCP plans and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

Mary Woleske

Mary H. Woleske, Director
Atlanta District

Enclosure